

## REMARKS

Claims 1-4 and 6-16 are pending in the present application. Applicant respectfully requests entrance of the above-amended claims, since no new matter has been added and the amendments move prosecution forward as will be explained below. Applicant reserves the right to file additional applications to canceled or amended subject matter, without prejudice.

Applicant has added "glycolipid" in Claims 1 and 6 as a point of clarification. Support is found on page 10, line 2. In Claims 7, 10, 11, 12, and 16, Applicant has amended the claims to address typographical errors, to correct improper claim dependency language, or to clarify the language. For example, in Claim 10, a neisserial infection is a type of gram negative bacterial infection and the claim language now reflects its proper dependency from Claim 9. In Claim 16, the word "consisting" was missing from the Markush group language and has been added. Further, in Claim 16, the phrase "of any one of claims 1-4" has been deleted as redundant and confusing, since that language appears in Claim 8, the independent claim. In Claim 7, the phrase "to impart enhanced immunity" has been added to reflect the language of the claim preamble. Applicant asserts that none of these amendments require additional searching or add new matter.

### Rejection under 35 U.S.C. § 112, second paragraph

Claims 1 and 6 have been rejected under 35 U.S.C. § 112, second paragraph, due to the phrase "suitable for oral or intranasal administration". In order to advance prosecution, Applicant has deleted the phrase from the claims. Therefore, they assert that this rejection is now moot and should be withdrawn.

### Rejection under 35 U.S.C. § 102(b)

Claims 1, 4, and 6 have been rejected as anticipated by U.S. Patent 4,707,543 (Zollinger) under 35 U.S.C. § 102(b). Applicant respectfully traverses, but in order to advance prosecution and place the claims into allowable form, he has amended the claims to specify that the lipopolysaccharide is non-detoxified. As stated by the Examiner in the Office Action, Zollinger is directed toward detoxified complexes rather than, as now claimed, non-detoxified. [Please see

the amended Claim 1 and 6.] As a result, Applicant respectfully requests the withdrawal of the anticipation rejection.

Rejection under 35 U.S.C. § 103(a)

The remaining claims (Claims 2, 3, and 7-16) have been rejected as obvious over Zollinger in view of Cohen, *et al.*, (*J. Infect. Dis.*, 1988, 157(5): 1068-1071) and Black, *et al.*, (*J. Infect. Dis.*, 1987, 155(6): 1260-1265) in view of Ruegg, *et al.*, (*J. Immunolog. Methods*, 1990, 135: 101-109). Applicant respectfully traverses. As stated above, the claims are directed toward non-detoxified lipopolysaccharides, which is unlike the detoxified lipopolysaccharides of Zollinger. The secondary references do not remedy the teachings of Zollinger in this regard, *i.e.*, they do not suggest the use of a non-detoxified lipopolysaccharide in the context of the invention as claimed.

Please note that U.S. Patent 5,985,284, the parent to the instant application, contains claims directed to non-detoxified antigenic lipopolysaccharides, and these claims issued over Zollinger. [For the Examiner's convenience, Applicant has attached a copy of the issued claims as Exhibit B.] Furthermore, in the reasons for allowance, the Examiner indicated that "Applicants have discovered that when native, 'toxic' LPS is formulated and administered with proteosomes described in the specification, it does not do harm to the animals as demonstrated. The present invention allows the delivery of native lipopolysaccharides that have not be chemically or otherwise detoxified. Further Applicant has shown that detoxified LPS was ineffective even when complexed to proteosomes and only non-detoxified LPS when complexed to proteosomes was immunogenic and protective."

For these reasons, Applicant respectfully requests the entrance and allowance of the pending claims.

Double-patenting rejection

All of the claims have been rejected under the judicially-created doctrine of obviousness-type double patenting in view of U.S. Patent 5,985,284. To overcome this rejection, Applicant

submits herewith a terminal disclaimer under 37 C.F.R. § 1.321. Therefore, this rejection has been overcome.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 406462000102. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

If the Examiner has any questions, please call the undersigned, Karen Dow, at (858) 720-7960, or send a facsimile to (858) 720-5125.

Respectfully submitted,

Dated: July 13, 2001

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Enclosed are the following Exhibits A-C:

Exhibit A - Version With Markings To Show Changes Made

Exhibit B - Claims of U.S. Patent 5,985,284

Exhibit C - Terminal Disclaimer under 37 CFR § 1.321

**EXHIBIT A: VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

1. (Twice amended) An immunogenic composition [suitable for oral or intranasal administration] comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes, [and] at least one non-detoxified antigenic lipopolysaccharide or glycolipid and a pharmaceutically acceptable carrier.

6. (Twice amended) A vaccine [suitable for oral or intranasal administration] comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes, [and] at least one non-detoxified antigenic lipopolysaccharide or glycolipid and a carrier.

7. (Twice amended) A method for providing enhanced immunogenicity comprising administering the immunogenic composition of any one of claims 1-4 or the vaccine of claim 6 to a subject orally or intranasally to impart enhanced immunity.

10. (Amended) A method of achieving immunity according to claim 9 wherein the [immunity is to] gram negative bacterial infection is a neisserial infection.

11. (Amended) A method of achieving immunity according to claim 10 wherein the [immunity is to] infection is a gonococcal infection.

12. (Amended) A method of achieving immunity according to claim 10 wherein the [immunity is to] infection is a meningococcal infection.

16. (Twice amended) A method of achieving immunity according to claim 8 by administering the immunogenic composition [of any one of claims 1-4] or the vaccine to mucosal surfaces selected from the group consisting of respiratory, gastrointestinal, vaginal, nasal, rectal and oral mucosa.